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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/922,181	08/02/2001	Mark E. Shannon	AEOMICA-012	7617

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EXAMINER	
GARVEY, TARA L	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 03/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/922,181	SHANNON ET AL.	
	Examiner	Art Unit	
	Tara L. Garvey	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-47* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-47 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11, 32, 33 and 39, drawn to a nucleic acid that encodes a zinc finger, probes, micorarray containing the probe, vector and host cell containing the nucleic acid and diagnostic and pharmaceutical composition of the nucleic acid, class 536, 23.1, class 435, subclasses 320.1 and 325.

II. Claim 12, drawn to a method of producing a polypeptide, classified in class 435, subclass 70.1.

III. Claims 13-18, 34, 35 and 40, drawn to a polypeptide, a fusion protein and diagnostic and pharmaceutical compositions of the polypeptide, classified in class 530, subclass 350.

IV. Claims 19, 36-38 and 41, drawn to an antibody and diagnostic and pharmaceutical compositions of the antibody, classified in class 435, subclass 180.1.

V. Claims 20, drawn to a transgenic animal, classified in class 800, subclass 8.

VI. Claims 21, drawn to a knock-out animal, classified in class 800, subclass 8.

VII. Claims 22 and 23, drawn to a method of identifying agents that modulate the expression of MDZ3, MDZ4, MDZ7 or MDZ12, classified in class 435, subclass 4.

VIII. Claims 24 and 42, drawn to a purified agonist and a pharmaceutical composition of the agonist, classified in class 530, subclass 350 and class 536, subclass 23.1.

IX. Claims 25 and 43, drawn to a purified antagonist and a pharmaceutical composition of the antagonist, classified in class 530, subclass 350 and class 536, subclass 23.1.

X. Claims 26 and 27, drawn to a method of identifying a specific binding partner, classified in class 435, subclass 4.

XI. Claim 28, drawn to a purified binding partner, classified in class 530, subclass 350.

XII. Claim 29, drawn to a method of detecting a target nucleic acid in a sample, classified in class 435, subclass 6.

XIII. Claim 30, drawn to a method of diagnosing a disease caused by a mutation in MDZ3, MDZ4, MDZ7 or MDZ12, classified in class 435, subclass 6.

XIV. Claim 31, drawn to a method of diagnosing or monitoring a disease caused by altered expression of MDZ3, MDZ4, MDZ7 or MDZ12 , classified in class 435, subclass 4.

XV. Claim 44, drawn to a method of treating or preventing a disorder associated with decreased expression or activity of MDZ3, MDZ4, MDZ7 or MDZ12, classified in class ***, subclass ***.

XVI. Claim 45, drawn to method of treating or preventing a disorder associated with increased expression or activity of MDZ3, MDZ4, MDZ7 or MDZ12, classified in class 514, subclass 44.

XVII. Claim 46, drawn to a method of modulating the expression of a nucleic acid, classified in class 435, subclass 6.

XVIII. Claim 47, drawn to a method of modulating at least one activity of a polypeptide, classified in class 435, subclass 4.

Groups I-VI, VIII-XII, XV-XVIII are comprised of multiple inventions, which are the products or methods drawn to different and distinct sequences, which do not render obvious each other and thus are patentably distinct. Please choose one combination of sequences from part (a) and (b) of claim 1 for inventions involving nucleic acid sequences. Additionally, if Group I is elected, choose a sequence for the probe of claim 4. Please choose one sequence from part (a) of claim 14 for inventions involving polypeptide sequences. Applicant must elect a single invention, which is the product or method drawn to one specific sequence to which the claims will be restricted. The applicant must also indicate which claims are readable on the elected invention.

Note: This restriction to examination of a single sequence is due to the now very high and undue burden for examining more than one sequence which is caused by the

continued exponential increase of size of the sequence databases to be searched for each sequence, resulting in a corresponding increase in computer search time and examiner time for reviewing the computer search results. Therefore, the limited resources of the Office no longer permit examination of more than one sequence in an application.

Note: the non-standard format of this restriction, separating the inventions into multi-invention groups drawn to distinct types of products and methods, followed by an election of a single invention drawn to one sequence within the elected multi-invention group was done for the sake of compactness of the communication and clarity, instead of using the more standard format setting forth each invention drawn to each separate sequence which would require a much longer and less clear communication.

The inventions are distinct, each from the other because of the following reasons:

The nucleic acid of Group I, the polypeptide of Group III, the antibody of Group IV, the transgenic animal of Group V, the knock-out animal of Group VI, the agonist of Group VIII, antagonist of Group IX and the binding partner of Group XI are chemically, biologically and functionally distinct from each other and thus one does not render the other obvious. The product of each group is not needed to produce the products of the other groups. Therefore, the inventions of these groups are capable of supporting separate patents.

The nucleic acid of Invention I are related to the transgenic animal of Invention V in that the animal can be produced using the nucleic acid of Invention I. The animal is distinct from the nucleic acid, however, because they are physically and functionally

distinct and the nucleic acid can be used for processes other than production of a transgenic animal, such as to express a protein or screen for compounds that bind to the protein. Furthermore, patentability of the transgenic animal arises from the phenotypic characteristics of the animal: thus, patentability of the transgenic animal is not solely dependent upon the particulars of the nucleic acid comprised within the animal.

Search and examination of the nucleic acid or a cell comprising the nucleic acid with the animal of Group V would impose an undue burden on the Office. Again, *prima facie* evidence of the additional burden is provided by the separate classification of the inventions. It is recognized in the office and in the art that transgenic organisms versus nucleic acids are a separate subject for inventive effort according to MPEP § 808.02(A). This is because, due to the highly unpredictable nature of genetic manipulation of multicellular organisms, mere possession of a nucleic acid or a cell comprising a nucleic acid does not support possession and enablement for multicellular organism comprising the nucleic acid or the cell.

Inventions of Groups II, VII, X and XII-XVIII are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of Groups II, VII and XII-XVIII comprise steps which are not required for or present in the methods of the other groups: producing a polypeptide (Group II), identifying agents that modulate the expression of MDZ3, MDZ4, MDZ7 or MDZ12 (Group VII), detecting a target nucleic acid in a sample (Group XII), identifying a specific binding partner (Group X), diagnosing a disease caused by a mutation in MDZ3, MDZ4,

MDZ7 or MDZ12 (Group XIII), diagnosing or monitoring a disease caused by altered expression of MDZ3, MDZ4, MDZ7 or MDZ12 (Group XIV), treating or preventing a disorder associated with decreased expression or activity of MDZ3, MDZ4, MDZ7 or MDZ12 (Group XV), treating or preventing a disorder associated with increased expression or activity of MDZ3, MDZ4, MDZ7 or MDZ12 (Group XVI), modulating the expression of a nucleic acid (Group XVII). The end result of each method is different. Thus, the operation, function and effects of these different methods are different and distinct from each other. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Inventions II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the polypeptide could be made by chemical synthesis.

Inventions II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the nucleic acid could be used as a probe to detect a nucleic acid in a sample.

Inventions XII and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the nucleic acid could be used to produce a protein in cell culture.

Inventions XV and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the nucleic acid could be used as a probe to detect a nucleic acid in a sample

Inventions III and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the polypeptide could be used in the treatment of a disease

Inventions III and XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product. See MPEP § 806.05(h). In the instant case, the polypeptide could be use to make an antibody.

Inventions VIII and XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the agonist can be used to study a signaling pathway in vitro.

Inventions IV and XVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case antibody can be used to diagnose a disorder.

Inventions IX and XVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the antagonist can be used to study a signaling pathway in vitro.

Except for the specific relationships described above, the inventions of Groups I, III-VI,VIII,IX and XI are chemically and Groups II, VII, X and XII-XVIII are unrelated.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different products of Groups I, III-VI,VIII, IX and XI are not used in or made by the methods of Groups II, VII, X and XII-XVIII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, by their recognized divergent subject matter and by a their requirement for different searches, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: different types of Zinc fingers (e.g. claims 22, 23, 30, 31, 44 and 45). Please choose one zinc finger-containing protein.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 22, 23, 30, 31, 44 and 45 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not

distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance,

whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tara L Garvey whose telephone number is (571) 272-

2917. The examiner can normally be reached on Monday through Friday 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) (http://pair-direct.uspto.gov) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

CELINE QIAN, PH.D.
PRIMARY EXAMINER

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tara L Garvey, Ph.D.
Examiner
Art Unit 1636

TLG